

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Center for Tobacco Products,
(FDA No. FDA-2016-H-2739)

Complainant

v.

Ramsajan LLC
d/b/a Avalon Liquors,

Respondent.

Docket No. T-16-1938

Decision No. TB2386

Date: January 17, 2018

INITIAL DECISION

I hereby impose a civil money penalty of \$3,500 against Respondent, Ramsajan LLC d/b/a Avalon Liquors, for five violations of federal tobacco regulations over a period of 36-months.

I. Background

The Center for Tobacco Products (CTP) began this matter by serving an administrative complaint on Respondent, Ramsajan LLC d/b/a Avalon Liquors, at 3588 Avalon Park East Boulevard, Suite 3, Orlando, Florida 32828, and by filing a copy of the complaint with the Food and Drug Administration's (FDA) Division of Dockets Management. The complaint alleges that Avalon Liquors impermissibly sold tobacco products to minors, and failed to verify, by means of photo identification containing a date of birth, that the purchasers were 18 years of age or older, thereby violating the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 et seq., and its implementing regulations, 21 C.F.R. pt. 1140. The complaint likewise alleges that Respondent Avalon Liquors was previously found liable for three violations of regulations found at 21 C.F.R. pt. 1140. *See*

Complaint at ¶¶ 1, 8, 10-11; *see also*, Informal Brief of Complainant at 1-2. Therefore, CTP seeks to impose a \$5,501 civil money penalty (“CMP”) against Respondent.

II. Procedural History

On October 4, 2016, Respondent timely filed an Answer (“Answer”) to CTP’s Complaint. On November 17, 2016, I issued an Acknowledgment and Pre-Hearing Order (“APHO”) that set out the deadlines for the parties’ submissions in this case, and issued informal briefs for the parties to complete and submit.¹

On April 19, 2017, CTP filed its pre-hearing exchange. CTP’s pre-hearing exchange included an Informal Brief of Complainant, a list of proposed witnesses and exhibits, and 19 marked exhibits. CTP’s exhibits included the declarations of two witnesses. Respondent did not file a pre-hearing exchange but did file several tax documents (“2015 Tax Return”) as well as a letter responsive to CTP’s discovery request (“Resp. Letter”).

On June 6, 2017, I held a pre-hearing conference in this case. During the prehearing conference, I explained that the sole purpose of a hearing under the applicable regulations was to allow for the cross- and re-direct examination of any witnesses who had provided sworn testimony in pre-hearing exchanges, and only if the opposing party elected to cross-examine the witness. Respondent’s representative Douglas Markovitz communicated his desire to cross-examine only one of CTP’s witnesses, Inspector Ivonne Rodriguez.

On August 30, 2017, I held a hearing in this case.² During the course of the hearing, I admitted CTP’s exhibits. Respondent cross-examined Inspector Rodriguez. *See* Hearing Transcript at 10-22.

On September 28, 2017, I informed the parties that the Court had received the transcript of the hearing, and set the deadline for the parties’ post-hearing brief submissions as October 27, 2017. Neither party filed a post hearing brief. As the briefing period is over, I now render my decision.

¹ I note the following discovery matters concerning Respondent’s Answer and CTP’s document requests. On January 27, 2017, CTP filed a Motion to Compel and a Motion to Extend Deadlines. In a February 3, 2017 letter, Respondent was granted until February 17, 2017, to respond to CTP’s Motion to Compel. CTP’s Motion to Extend Deadlines was granted on February 3, 2017. On March 1, 2017, Respondent filed a response to CTP’s Motion and documents related to their request. On March 13, 2017, CTP filed another Motion to Extend Deadlines which I granted on March 16, 2017.

² I note that on August 8, 2017, Respondent’s representative requested to reschedule the hearing from August 10, 2017 due to a prescheduled medical procedure.

III. Issues

- A. Whether Respondent Avalon Liquors sold tobacco products to a minor and failed to verify that the tobacco product purchaser was of sufficient age, on February 26, 2016, in violation of 21 C.F.R. §§ 1140.14(a)(1), (a)(2)(i).
- B. Whether a civil money penalty of \$5,501 is reasonable.

IV. Applicable Regulations and Guidelines

CTP determined to impose a CMP against Respondent pursuant to the authority conferred by the Federal Food, Drug, and Cosmetic Act (Act) and implementing regulations at Part 21 of the Code of Federal Regulations (C.F.R.). The Act prohibits the misbranding of tobacco products while they are held for sale after shipment in interstate commerce. 21 U.S.C. § 331(k). The Food and Drug Administration and its agency, CTP, may seek civil money penalties from any person who violates the Act's requirements as they relate to the sale of tobacco products. 21 U.S.C. § 331(f)(9). The sale of tobacco products to an individual who is under the age of 18 and the failure to verify the photographic identification of an individual who is not over the age of 26 are violations of implementing regulations. 21 C.F.R. §§ 1140.14(a)(1), (a)(2).

In order to prevail, CTP must prove Respondent's liability by a preponderance of the evidence. The Supreme Court has described the preponderance of the evidence standard as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Products of California, Inc. v. Construction Laborers*, 508 U.S. 602, 622 (1993).

I find that under 21 U.S.C. § 333(f)(9), I have the authority to impose a CMP.

V. Analysis

A. Alleged Violations, Parties' Contentions, and Findings of Fact

CTP alleges that Respondent committed five violations of the Act and its implementing regulations over a thirty-six month period. Complaint at ¶ 1.

In its Complaint, CTP alleged that at approximately 4:45 p.m. on February 26, 2016, at Respondent's business establishment, 3588 Avalon Park East Boulevard, Suite 3, Orlando, Florida 32828, an FDA commissioned inspector documented Respondent's staff selling a package of Newport cigarettes to a person younger than 18 years of age. Complaint at ¶ 3; *see also*, Informal Brief of Complainant at 3. The inspector also

documented that staff failed to verify, by means of photographic identification containing a date of birth, that the purchaser was 18 years of age or older. *Id.*

In its Answer, Respondent denies the latest alleged violations. Answer at 2. Respondent also requests that “the fine imposed be greatly reduced or removed from its record.” *Id.*

1. Parties’ Contentions and Evidence

CTP’s case against Respondent relies on the testimony of Inspector Rodriguez, who accompanied by a confidential state-contracted minor (“Minor FLUP1519”), conducted an undercover buy portion of a follow-up compliance check inspection at Avalon Liquors, on February 26, 2016. Informal Brief of Complainant at 3. As evidence,³ CTP provided a sworn declaration from Inspector Rodriguez. *See* CTP Ex. 3 (Rodriguez Declaration). Inspector Rodriguez is an FDA-commissioned officer with INS Corporation. *Id.* at ¶ 2. Her duties include conducting undercover inspections to determine whether retailers comply with the age and photographic identification requirements relating to the sale of tobacco. *Id.* at ¶¶ 1-2. CTP provided a copy of the Compliance Check Inspection Notice (CTP Ex. 16); Inspector Rodriguez’s Narrative Report of the undercover inspection, Narrative Report (CTP Ex.7); the TIMS Form (CTP Ex. 6); and a redacted copy of the Minor FLUP1519’s identification (CTP Ex. 5). Finally, Respondent cross-examined Inspector Rodriguez at the August 30, 2017 hearing. *See* Hearing Transcript at 10-22.

Respondent denies the allegations in its pleadings, but has provided no evidence to refute that the alleged violations on February 26, 2016, occurred. During the hearing, Respondent’s cross-examination of Inspector Rodriguez centered on questions regarding the background and experience of the investigator and the minor; how stores are selected for inspection; and whether the investigative team have special incentives for reporting violations. *See* Hearing Transcript at 10-22.

Regarding the transaction on February 26, 2016, Inspector Rodriguez testified as follows:

Q. Okay. Do you remember how this particular situation went?

A. That I remember, there was a gentleman sitting outside on a bench. Your business has two entrances and we went into the business in different doors. So your employee entered one side. I enter [sic] the other side with the minor. I looked around, you know, for the product, let’s say, and the minor requested cigarettes to your employee. And that I remember he did not request an identification and he did not provide a receipt. And after that we exited the business and the product was given to me so it could be processed.

³ The evidence discussed in this paragraph is not exhaustive.

Q. What did the clerk look like?

A. That I remember, it's a tall gentleman, possibly African-American, brown hair, dark eyes, perhaps slender. But that's to the extent that I remember at this moment.

Hearing Transcript at 18-19.

2. Findings of Fact

I find that Inspector Rodriguez testified credibly and comprehensively about her observations during the February 26, 2016, inspection at which she observed Respondent selling tobacco products to Minor FLUP1519. *See* Hearing Transcript at 18 -19; CTP Ex. 3; CTP Ex. 7. Based on the record as a whole, I conclude that CTP has established by a preponderance of the evidence that Respondent: (1) sold tobacco products to a Minor FLUP1519 on February 26, 2016; and (2) failed to verify that tobacco product purchaser was of sufficient age, in violation of 21 C.F.R. § 1140.14(a)(1) and 21 C.F.R. § 1140.14(a)(2)(i).

Therefore, I find that CTP has met its burden to establish Respondent Avalon Liquors' liability under the Act for five violations within a 36-month period.

B. Civil Money Penalty

Pursuant to 21 U.S.C. § 333(f)(9), Respondent Avalon Liquors is liable for a CMP not to exceed the amounts listed in FDA's civil money penalty regulations at 21 C.F.R. § 17.2. In its Complaint, CTP sought to impose the maximum penalty amount, \$5,501, against Respondent for five violations of the Act and its implementing regulations within a thirty-six month period. Complaint at ¶ 1. When determining the amount of a CMP, I am required to take into account "the nature, circumstances, extent and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require." 21 U.S.C. § 333(f)(5)(B).

1. Nature, Circumstances, Extent and Gravity of the Violations

I have found that Respondent committed a total of five violations of FDA tobacco regulations within a period a 36-month period. The repeated inability of Respondent to comply with federal tobacco regulations is serious in nature and the CMP should be set accordingly.

2. Respondent's Ability to Pay

Respondent asserts that it believes the CMP sought is “unreasonable and will significantly hurt our business and cash flow.” Resp. Letter at 1. Respondent states that “any sort of major fine from the FDA would be very detrimental to our business cash flow and cause us great harm in the near future.” *Id.* at 2. As part of the discovery process, Respondent filed a copy of its 2015 Form 1120S (U.S. Income Tax Return for an S Corporation), [REDACTED], 2015 Tax Return. [REDACTED]

[REDACTED] Furthermore, the tax return is for 2015 and not 2016 when the alleged violations occurred. *See* 2015 Tax Return. Nonetheless, I will take the documentation [REDACTED] into account when setting the penalty amount.

3. Effect on Ability to do Business

There is nothing in the evidentiary record that clearly establishes the effect a CMP will have on Respondent's ability to do business. However, Respondent's [REDACTED] [REDACTED] is sufficiently compelling to support a finding that justice requires some reduction of the penalty amount in this particular case.

4. History of Prior Violations

It is undisputed that Respondent is a repeated violator of FDA's tobacco regulations prohibiting the sale of tobacco products to minors. The current action is the second civil money penalty action that CTP has brought against Respondent. While Respondent has already paid a CMP for its previous violations, its continued inability to comply with the federal tobacco regulations calls for a more severe penalty. In addition to the two current violations on February 26, 2016, Respondent has twice before violated the prohibition against selling tobacco products to persons younger than 18 years of age, 21 C.F.R. § 1140.14(a)(1), and twice before violated the requirement that retailers verify, by means of photo identification containing a purchaser's date of birth, that no tobacco purchasers are younger than 18 years of age, 21 C.F.R. § 1140.14(a)(2)(i). The first civil money penalty action was decided by default when Respondent failed to answer. *See* Complaint at ¶¶ 1, 10-11.

5. Degree of Culpability

Based on my finding that Respondent committed the most recent violations as alleged in the current complaint, I hold it fully culpable for all five violations of the Act and its implementing regulations.

6. *Additional Mitigating Factors*

I do not find any mitigating factors. Respondent has not provided any evidence that it has implemented new policies for its employees about when to verify the age of tobacco product purchasers. Respondent asserts that it has posted “FDA signage and state documents...behind the counter... [E]ncouraged employees to check IDS to anyone that looks in there [sic] 20s and refuse sale if necessary for failure to provide identification,” and has put “all new employees in place in February 2016.” Resp. Letter at 1. While Respondent may indeed have hired new employees that it has “encouraged” to check customer identification, these efforts have proven ineffective in Respondent’s establishment.

7. *Penalty*

Based on the foregoing reasoning, I find a reduced penalty amount of \$3,500 to be reasonable and appropriate under 21 U.S.C. §§ 303(f)(5)(B).

VI. Conclusion

For these reasons, I enter judgment in the amount of \$3,500 against Respondent, Ramsajan LLC d/b/a Avalon Liquors, for five violations of the Federal Food, Drug, and Cosmetic Act (Act), 21 U.S.C. § 301 *et seq.*, and its implementing regulations, 21 C.F.R. pt. 1140, within a thirty-six month period. Pursuant to 21 C.F.R. § 17.11(b), this order becomes final and binding upon both parties after 30 days of the date of its issuance.

/s/
Catherine Ravinski
Administrative Law Judge